

## **APPENDIX A: PROCEDURES**

### **1. Notification of Threats and Notifying ORI of Special Circumstances**

Throughout these proceedings, the RIO will periodically determine if any threat of harm to public health, federal funds and equipment, or the integrity of the PHS supported research process exists. If a threat is identified, the RIO will, in consultation with other agency officials and ORI, take appropriate interim action to protect against such threat. Interim action might include additional monitoring of the research process (e.g., notification of the CDC Human Research Protections Office and/or HHS Office for Human Research Protection), additional monitoring of the handling of federal funds and equipment, reassignment of personnel or the responsibility for the handling of federal funds and equipment, additional review of research data and results or delaying publication. At any point in the process, the RIO shall notify ORI immediately if (s)he has reason to believe that any of the following exist:

- Health or safety of the public is at risk, including an immediate need to protect human or animal subjects;
- HHS resources or interests are threatened;
- Possible violations of civil or criminal law exist;
- Federal action is required to protect the interests of those involved in the research misconduct proceeding;
- The research misconduct proceeding may be made public prematurely and HHS action may be necessary to safeguard evidence and protect the rights of those involved; or
- The research community or public should be informed.

### **2. Protecting the Respondent**

As appropriate, the RIO and other agency officials shall make reasonable and practical efforts to protect or restore the reputation of respondents alleged to have engaged in research misconduct, but against whom no finding of research misconduct is made. Depending on the particular circumstances and the views of the respondent, the RIO may consider actions such as: notifying those individuals aware of or involved in the proceedings of the final outcome, and/or expunging reference to the research misconduct allegation from the respondent's personnel file, etc. Agency actions to restore the respondent's reputation must be approved by the CDC Deciding Official (DO).

During the research misconduct proceeding, the RIO is responsible for ensuring

that respondents receive notices and opportunities provided for in 42 CFR Part 93 and the policies and procedures of the agency. Respondents may consult with personal legal counsel or a non-lawyer personal adviser and may bring these individuals to interviews or meetings on the case. Representatives from either the CDC Office of the General Counsel or the Atlanta Human Resources Center will also be available, on behalf of the agency, to review reports and other documents and to attend meetings if/as appropriate.

#### *Admissions of research misconduct*

If at any point in the process, the respondent(s) admits to the misconduct, (s)he should sign a written statement attesting to the misconduct. The respondent(s) should acknowledge that the statement was voluntary. The admission may not be used as a basis for closing an inquiry or investigation unless the designated steps for completion have been met pursuant to 42 C.F.R. § 93.316.

### **3. Conducting the Assessment and Inquiry**

#### **A. Assessment of Allegations**

Upon receiving a written allegation of research misconduct, the RIO will assess the allegation to determine whether it is sufficiently credible and specific. If the allegation falls within the jurisdictional criteria of 42 CFR § 93.102(b), and the definition of research misconduct in 42 CFR § 93.103, then an inquiry must be conducted.

The assessment period should be brief, preferably concluded within seven calendar days. The RIO need not interview the complainant, respondent, or other witnesses, gather or review data beyond that submitted with the allegation, except as necessary to determine whether the allegation is sufficiently credible and specific so that potential evidence of research misconduct may be identified.

#### **B. Initiation and Purpose of the Inquiry**

If the RIO determines that an inquiry is warranted, the RIO will initiate the inquiry process. The purpose of the inquiry is to conduct an *initial* review of the available evidence to determine whether an investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible.

#### **C. Notice to Respondent; Storage of Research Records**

At the time of or before beginning an inquiry, the RIO must make a good faith effort to notify the respondent(s) in writing, if the respondent is known. On or before the date on which the respondent is notified, or the inquiry begins, whichever is earlier, the RIO must take reasonable and practical steps to obtain custody of the research records and evidence needed to conduct the research

misconduct proceedings. For research records or evidence contained within scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, if copies are substantially equivalent to the evidentiary value of the originals.

Records of the research misconduct proceeding, as defined in 42 CFR 93.317, are to be stored in a secure manner for seven years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained. All records in CDC custody will be secured in accordance to standard federal regulations 36 CFR Part 1220.

#### **D. Appointment of the Inquiry Committee**

The RIO will appoint an inquiry committee and committee chair within seven calendar days after the assessment period. The inquiry committee should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. Committee members should not have any unresolved personal, professional, or financial conflicts of interest with those involved with the inquiry and will document these facts in writing. The RIO will notify the respondent of the proposed committee membership to give the respondent an opportunity to object to a proposed member based upon a personal, professional, or financial conflict of interest. The respondent should submit any objection to the RIO within 10 calendar days. The RIO will make the final determination of whether a conflict exists.

#### **E. Charge to the Committee and First Meeting**

The RIO will prepare a charge for the inquiry committee that:

- States the purpose of the inquiry;
- Describes the allegations and related issues identified during the allegation assessment;
- Informs the inquiry committee of their roles and responsibilities, including the preparation of a written report; and
- Sets forth the timeline for completion of the inquiry.

At the committee's first meeting, the RIO will review the charge with the committee, discuss the allegations, related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions. A copy of this policy and 42 CFR 93 will be provided to the committee. The RIO will be present or available

throughout the inquiry to advise the committee as needed.

#### **F. Inquiry Process**

The inquiry committee will interview the complainant, the respondent and key witnesses as well as examine relevant research records and materials. In consultation with the RIO, the committee will recommend whether an investigation is warranted based on the criteria in this policy and 42 CFR Part 93. In general, the scope of the inquiry does not include determining whether misconduct definitely occurred, determining definitely who committed the research misconduct or conducting exhaustive interviews and analyses. However, if a legally sufficient admission of research misconduct is made by the respondent, misconduct may be determined at the inquiry stage. In that case the RIO shall promptly consult with ORI to determine the next steps.

#### **G. Elements of the Inquiry Report**

The written inquiry report must meet the requirements of 42 CFR Part 93 and include the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) the CDC support, including, for example, grant numbers, grant applications, contracts and publications listing CDC support; (4) the basis for recommending or not recommending that the allegations warrant an investigation; (5) any comments on the draft report by the respondent or complainant.

The inquiry report may also include: the names and titles of the committee members and experts who conducted the inquiry; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; and whether any other actions should be taken if an investigation is not recommended.

#### **H. Notification to the Respondent, Complainant(s), Witness(es), and Opportunity to Comment**

Within 10 calendar days following submission of the report, the RIO shall notify the respondent, complainant(s), and witness(es) whether the committee recommended further investigation, provide a copy of the draft inquiry report for comment, and provide a copy of or refer to 42 CFR Part 93 and CDC's policies and procedures on research misconduct. The respondent, complainant(s), and witness(es) shall have seven calendar days to comment on the draft report.

The inquiry committee may revise the report as per the respondent's comments or attach the respondent's comments to the final report. The committee delivers the final inquiry report to the RIO.

#### **I. CDC Decision and Notification**

### 1) Decision by CDC Deciding Official

Within seven calendar days the RIO transmits the final inquiry report and any comments to the Agency Deciding Official (CDC Chief Science Officer). The CDC Chief Science Officer makes the final determination whether an investigation is warranted. This decision is documented in writing and signals the completion of the inquiry process.

### 2) Notification to ORI

As soon as possible, but within 30 calendar days of the CDC Chief Science Officer's decision that an investigation is warranted, the RIO provides ORI with the CDC Chief Science Officer's written decision and a copy of the inquiry report. The RIO also notifies agency officials who need to know of the CDC Chief Science Officer's decision. The RIO must provide the following information to ORI upon request: (1) the agency policies and procedures under which the inquiry was conducted; (2) the research records and evidence reviewed, transcripts or recordings of any interviews, and copies of relevant documents; and (3) the charges to be considered in the investigation.

### 3) Documentation of Decision Not to Investigate

If the CDC Chief Science Officer decides that an investigation is not warranted, the RIO shall secure and maintain sufficiently detailed documentation of the inquiry for seven (7) years. These documents must be provided to ORI or other authorized HHS personnel upon request as per 42 CFR 93.317.<sup>1</sup>

### 4) Time for Completion

The inquiry, including preparation of the final report and the decision of the CDC Chief Science Officer about whether an investigation is warranted, must be completed within 60 calendar days, unless extenuating circumstances (e.g., illness, other emergencies) clearly warrant a longer period. If the committee becomes aware of circumstances requiring an extension, the RIO should be notified immediately and propose a new timeline. If the RIO approves an extension, the inquiry record must include documentation of the reasons for exceeding the 60 days.

## **4. Conducting the Investigation**

### **A. Initiation and Purpose**

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<sup>1</sup> See additional information in references G,H and I in policy "responding to Allegations of Research Misconduct"

The investigation must begin within 30 calendar days after the determination by the CDC Chief Science Officer that an investigation is warranted. The purpose of the investigation is to explore the allegations in detail and examine the evidence in depth, to determine whether research misconduct has been committed, by whom, and to what extent.

**B. Notifying ORI, Respondent, and Supervisor(s); Storage of Research Records**

On or before the date on which the investigation begins, the RIO must:

- 1) Notify ORI of the decision to begin the investigation and provide a copy of the inquiry report; and
- 2) Notify the respondent in writing of the allegations to be investigated. The RIO must also give the respondent written notice of any new allegations of research misconduct not addressed during the inquiry or in the initial notice of the investigation. The notification includes: a copy of the Inquiry Report; the specific charges of research misconduct; the definition of research misconduct; the procedures to be followed in the investigation, including the appointment of the Investigation Committee and experts; the opportunity for the respondent(s) to be interviewed, to provide information, to be assisted by counsel or by a union representative if appropriate, to challenge the membership of the Committee and experts based on bias or conflict of interest, and to comment on the draft Report; the fact that ORI will perform an oversight review of the report; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board if a finding of research misconduct is made.
- 3) Notify Supervisors - the immediate supervisors of the respondent, complainant, and expert witnesses will be notified that an allegation of scientific misconduct has been made which requires their employee(s) to meet with an investigation committee. Supervisors will not be told the exact nature of the employee's role in the evaluation of the allegation. Supervisors will assure that their employees' participation in the investigation does not affect any performance evaluation.
- 4) Store Research Records and Evidence -- prior to notifying the respondent, the RIO will take reasonable and practical steps to obtain and securely store any additional research records and evidence that were not previously stored during the inquiry. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent to the evidentiary value of the instruments. The procedures to be followed for

storage during the investigation are the same procedures that apply during the inquiry.

### **C. Appointment of the Investigation Committee**

The RIO will appoint an investigation committee and the committee chair within 10 days of the beginning of the investigation. Investigation Committee members should not have any unresolved personal, professional, or financial conflicts of interest with those involved with the investigation. The Investigation Committee should consist of at least five voting members who have the necessary expertise and training to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons. The committee should reflect a racial and gender balance whenever possible. All committee members must sign a statement indicating that no personal financial or professional conflicts of interest exist with respect to the respondent, complainant, or the case in question. One member of the Investigation Committee will be a person of similar professional designation as the respondent (e.g., another postdoctoral fellow if the respondent(s) is a postdoctoral fellow). Experts may be appointed (or carried over from the Inquiry if no objection is raised) to advise the committee on scientific or other issues. The respondent(s) may suggest other experts. Experts cannot vote within the committee.

Option: When necessary to secure the necessary expertise or to avoid conflicts of interest, the RIO may select committee members from outside the institution.

Option: As an alternative, the institution may appoint a standing committee authorized to add or reuse members or use consultants when necessary to evaluate specific allegations.

### **D. Objection to Committee or Experts by Respondent(s)**

The RIO will notify the respondent(s) of the proposed committee membership as soon as it has been established. If the respondent(s) objects to the Committee's suggested membership, a written objection listing specific reasons, must be submitted to the RIO within 10 calendar days. The RIO will then determine whether there is any bias or conflict of interest that would necessitate replacing the challenged member.

### **E. Charge to the Committee and the First Meeting**

#### **1) Charge to the Committee**

The RIO will prepare a charge to committee which:

- States the purpose of the investigation;

- Describes the allegations and related issues identified during the inquiry;
- Informs the committee of their roles and responsibilities, including the preparation of a written report and;
- Sets forth the time line for completion of the investigation

## 2) First Meeting

The RIO will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing an Investigation Plan as soon as possible. The Investigation Plan includes, but is not limited to: an inventory of all previously securely stored evidence and testimony; a determination of whether additional evidence needs to be securely stored; a list of witnesses to be interviewed, including the complainant(s) and respondent, and a list of other witnesses with knowledge of the events; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and a plan for the Investigation Report. The investigation committee will be provided with a copy of this policy and 42 CFR Part 93. The RIO and other agency officials (e.g., staff from the CDC Office of General Counsel) will be available throughout the investigation to advise the committee as needed.

## 3) Investigation Process

At least two or more investigation committee members interview each respondent, complainant, and any other available person(s) with relevant information as well as examines research records and evidence. The committee ensures the interviews and record review are sufficiently documented.

## F. Elements of the Investigation Report

The written investigation report must meet the requirements of 42 CFR Part 93 and include the following information: (1) The name and position of the respondent, (2) a description of the allegations of research misconduct; (3), the CDC support, including, for example, contract number(s), or publications listing CDC support; (4) the agency policies and procedures under which the investigation was conducted, unless those policies and procedures were provided to ORI previously; (5) a summary of the research records and evidence reviewed and a description of any evidence taken into custody but not reviewed; and (6) a statement of findings for each allegation of research misconduct

identified during the investigation.

The statement of findings must: (1) identify the type of research misconduct (falsification, fabrication, or plagiarism), and whether it was committed intentionally, knowingly, or recklessly; (2) summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent, including any effort by the respondent to establish by a preponderance of the evidence that (s)he did not engage in research misconduct because of honest error or a difference of opinion; (3) identify the specific CDC support; (4) identify whether any publications need correction or retraction; (5) identify the person(s) responsible for the misconduct; and (6) list any current support or known applications or proposals for support that the respondent has pending with non-CDC federal agencies.

#### **G. Comments on the Draft Report and Access to Evidence**

##### **1) Respondent**

The RIO shall give the respondent both a copy of the draft investigation report for comment and a copy of, or supervised access to, the evidence on which the report is based. The respondent will be allowed 30 calendar days from the date of receipt to submit comments to the RIO. The respondent's comments must be included and considered in the final report.

##### **2) Complainant**

The RIO shall provide the complainant a copy of the draft investigation report, or relevant portions of it, for comment. The complainant's comments must be submitted within 30 calendar days of the date on which he/she received the draft report and the comments must be included and considered in the final report.

#### **H. Decision by CDC Chief Science Officer**

The RIO will transmit the final investigation report to the CDC Chief Science Officer, who will determine in writing: (1) whether the institution accepts the investigation report and its findings; and (2) the appropriate agency actions in response to the accepted findings of research misconduct. Examples of agency actions may include: 1) withdrawal or correction of pending or published abstracts and papers emanating from the research misconduct; 2) removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment; or 3) other action appropriate to the misconduct.

If the determination by the CDC Chief Science Officer varies from the findings of the investigation committee, the CDC Chief Science Officer will explain the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the CDC Chief Science Officer may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached by the DO, the RIO will notify both the respondent and the complainant in writing, and inform ORI. The RIO and other agency officials will also determine if law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should also be notified of the outcome of the case. The RIO is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

#### **I. Time for Completion**

The investigation is to be completed within 120 calendar days, including submission of the final report to ORI. If extenuating circumstances (e.g., illness, other emergency) warrant a longer period, the RIO should be notified. In this case, the RIO should propose a new timeline and submit a written request for extension that includes the reasons for the delay. If ORI approves the extension, the RIO will ensure that periodic progress reports are filed with ORI as requested.

#### **J. Appeals**

The respondent may appeal the decision by submitting a written request to the RIO within 30 calendar days. If an appeal is filed, it must be acted upon within 120 days of its filing, unless ORI finds good cause for an extension, based upon the institution's written request. If ORI grants an extension, it may direct the filing of periodic progress reports. The appeal process will be as follows:

Respondent submits a written request to the RIO

- 1) The RIO reviews and determines whether the request is appropriate
- 2) If an appeal is warranted, the RIO forwards the request to the investigation committee for review
- 3) The investigation committee and the RIO make a decision
- 4) The CDC Chief Science Officer reviews the decision and makes a final recommendation

#### **K. Notice to ORI of Agency Findings and Actions**

Unless an extension has been granted, the RIO must, within the 120-day period for completing the investigation or the 120-day period for completion of any appeal, submit the following to ORI: (1) a copy of the final investigation report with any attachments and any appeal; (2) a statement of whether the agency

accepts the findings of the investigation report or the outcome of the appeal; (3) a statement of whether the agency found misconduct and, if so, who committed the misconduct; and (4) a description of any pending or completed administrative actions against the respondent.

#### **L. Maintaining Records for Review by ORI**

The RIO must maintain and provide to ORI upon request “records of research misconduct proceedings” as that term is defined by 42 CFR § 93.317. These records are to be stored in a secure manner for seven years after completion of the proceeding, or the completion of any ORI proceeding involving the allegation of research misconduct, whichever is later, unless custody of the records has been transferred to ORI or ORI has advised that the records no longer need to be retained in accordance with an approved records control schedule. All records in CDC custody will be secured and preserved in accordance with standard federal regulations 36 CFR Parts 1220 and 1228.

The RIO is also responsible for providing any information, documentation, research records, evidence or clarification requested by ORI to carry out its review of an allegation of research misconduct or of the agency’s handling of such an allegation.

### **5. Completion of Cases; Reporting Closures to ORI**

Generally, inquiries and investigations will be carried through to completion. The RIO must notify ORI of plans to close a case at the inquiry, investigation, or appeal stage on the basis that respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason, except: (1) closing of a case at the inquiry stage on the basis that an investigation is not warranted; or (2) a finding of no misconduct at the investigation stage, which must be reported to ORI, as prescribed in this policy and 42 CFR § 93.315.

### **6. Other Considerations**

#### **A. Termination or Resignation Prior to Completing Inquiry or Investigation**

The termination or resignation of the respondent, before or after an allegation of possible research misconduct has been reported, will not preclude or terminate the research misconduct proceeding or otherwise limit any of the agency’s responsibilities under 42 CFR Part 93.